

Application No.: 09/446783
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Attorney Docket No.: VPHAR1460-2
(071243-1301)

REMARKS

The present invention relates to articles of manufacture and formulations for the in vivo delivery of substantially water insoluble pharmacologically active agents in nanoparticle form (e.g., the anticancer drug paclitaxel).

By the present communication, claims 102 and 103 have been amended to define Applicants' invention with greater particularity and not in response to any prior art. These amendments do not introduce new matter as they are fully supported throughout the specification and claims as originally filed. Claim 106 is canceled herein without prejudice. Applicant reserves the right to file divisional application(s) to any canceled subject matter. Accordingly, claims 29-35, 46-67, 70-105 and 107-120 are still pending in this application, with claims 73-75, 101-105, 107 and 108 under active consideration. The present status of all claims in the application is provided in the listing of claims presented herein beginning on page 3.

Rejection of claims 73-75, 101-104, 107 and 108 under 35 U.S.C. §102(b) and claims 73, 102, 103, 107 and 108 under 35 U.S.C. §102(e)

The rejections of claims 73-75, 101-104, 107 and 108 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,439,686 issued to Desai *et al.* (hereinafter referred to as "Desai") and claims 73, 102, 103, 107 and 108 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,897,879 (based on a priority date of May 3, 1994) issued to Friedman *et al.* (hereinafter referred to as "Friedman"), are respectfully traversed. It is respectfully submitted that these rejections have been rendered moot by the amendments submitted herewith. Thus, the present application, as amended herewith, claims priority to Desai, which has priority to February 22, 1993 (see, Table 1 below).

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TABLE 1

Priority of the Present Application	
U.S. Appl. No. 09/446,783:	May 16, 2000
PCT/US98/13272	June 26, 1998
U.S. Appl. No. 08/926,155 (U.S. Pat. No. 6,096,331)	September 9, 1997
U.S. Prov. Appl. No. 60/051,021 (abandoned)	June 27, 1997
U.S. Appl. No. 08/720,756 (U.S. Pat. No. 5,916,596)	October 1, 1996
U.S. Appl. No. 08/485,448 (U.S. Pat. No. 5,665,382)	June 7, 1995
U.S. Appl. No. 08/412,726 (U.S. Pat. No. 5,560,933)	March 29, 1995
U.S. Appl. No. 08/200,235 (U.S. Pat. No. 5,498,421)	February 22, 1994
U.S. Appl. No. 08/035,150 (U.S. Pat. No. 5,362,478)	March 26, 1993
U.S. Appl. No. 08/023,698 (U.S. Pat. No. 5,439,686)	February 22, 1993

In addition, Applicants are submitting herewith a Petition to Accept an Unintentionally Delayed Domestic Priority Claim under 37 C.F.R. §1.78(a)(3); and a supplemental Oath and Declaration (an unexecuted copy of which is enclosed herewith for the Examiner's convenience; fully executed copy to be provided in due course), to claim the benefit of the earlier-filed application. Accordingly, neither Friedman nor Desai are prior art to the present claims. Reconsideration and withdrawal of these rejections are respectfully requested.

Rejection of claims 73-75, 101-104 and 106-108 under 35 U.S.C. § 102(e)

The rejection of claims 73-75, 101-104 and 106-108 under 35 U.S.C. §102(e), as allegedly being anticipated by U.S. Patent No. 5,945,033 issued to Yen *et al.* (hereinafter referred to as "Yen"), is respectfully traversed.

The rejection of claim 106 is rendered moot by the cancellation of this claim herein.

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Applicants' invention, as defined for example by claim 73, distinguishes over Yen at least by requiring the formulation of a drug and at least one protein, wherein the drug is in nanoparticle size. Yen does not disclose the formulation of claim 73. Instead, Yen discloses mixtures of nanometer and micrometer size particles of albumin and hemoglobin. Indeed, none of the formulations disclosed in Yen contain a drug in nanoparticle size and a protein.

As shown in Table 2 below, Yen is a continuation of U.S. Pat. Appl. No. 08/212,564, now U.S. Pat. No. 5,616,311, which is a continuation-in-part of U.S. Pat. Appl. No. 08/069,831, now abandoned, and U.S. Pat. Appl. No. 07/959,560, now U.S. Pat. No. 5,308,620 (herein after referred to as the "'620 patent'"), which is a continuation of U.S. Pat. Appl. No. 07/641,720, now abandoned.

TABLE 2

Priority of Yen	
Yen et al. (U.S. Pat. No. 5,945,033)	November 12, 1996
U.S. Pat. Appl. No. 08/212,546 (U.S. Pat. No. 5,616,311)	March 14, 1994
U.S. Pat. Appl. No. 08/069,831 (Abandoned)	June 1, 1993
U.S. Pat. Appl. No. 07/959,560 (U.S. Pat. No. 5,308,620)	October 13, 1992
U.S. Pat. Appl. No. 07/641,720 (Abandoned)	January 15, 1991

It is respectfully submitted that while Yen's earliest claim for priority dates back to January 15, 1991 (for the subject matter disclosed in U.S. Pat. Appl. No. 07/641,720), the Yen disclosure relevant to the present claims was not introduced until at least June 1, 1993. As described above, claim 73 distinguishes over Yen at least by requiring the formulation of a drug and at least one protein, wherein the drug is in nanoparticle size. The '620 patent, however, discloses nanomatrixes, prepared from hemoglobin, albumin and an alcohol solvent, which vary widely, i.e., from less than 0.05 microns to larger than 1 micron in diameter, and are useful for entrapping biologically active substances for in vivo administration (see, Abstract and col. 5 lines 11-20). Indeed, none of the formulations disclosed in the '620 patent contain a drug in

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nanoparticle size and a protein. Accordingly, reconsideration and removal of this rejection is respectfully requested.

Rejection of claims 73-75, 101-104 and 106-108 under 35 U.S.C. § 103(a) and claim 105 under 35 U.S.C. § 103(a)

The rejections of claims 73-75, 101-104 and 106-108 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,143,276 (based on a priority date of March 21, 1997) issued to Unger *et al.* (hereinafter referred to as "Unger") and claim 105 under 35 U.S.C. § 103(a) as allegedly being obvious over Unger further in view of U.S. Patent No. 5,731,355 (based on a priority date of March 22, 1994) issued to Jones *et al.* (hereinafter referred to as "Jones"), are respectfully traversed. It is respectfully submitted that these rejections have been rendered moot by the amendments submitted herewith. Thus, the present application, as amended herewith, claims priority to Desai, which has priority to February 22, 1993 (see, Table 1, *supra*). Accordingly, neither Unger nor Jones are prior art to the present claims. Reconsideration and withdrawal of these rejections are respectfully requested.

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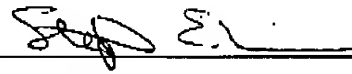
Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: November 3, 2003

By: _____


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Enclosures:

Petition to Accept an Unintentionally Delayed Domestic Priority Claim under 37 C.F.R.
§1.78(a)(3);

Supplemental Oath and Declaration